REMARKS

Claims 1-47 are pending in this application. The Examiner has withdrawn claims 46 and 47 as being drawn to nonelected subject matter. The Examiner has allowed claim 21 and has raised only formal objections to claims 1-5, 9-11, and 19. Claims 6-8, 12-18, 20, and 22-25 are rejected.

With this reply, Applicants have cancelled claims 27, 32, 41, 43, 46, and 47. Applicants have amended claims 1, 12-16, 20, 23-25, 28-31, 35, 37, 38, and 42. The amendments do not add new matter.

Claim Objections

The Examiner has objected to claims 1-16, 19, 24-34, 39-40, and 42-45 for reciting "BAFF" and "BAFF-R" without first "defining what they represent in the independent claims." Applicants have amended claim 1 to indicate that the term "BAFF" is derived from "B-cell-activating factor of the TNF family" and that the term "BAFF-R" is derived from "BAFF receptor." Support for these amendments can be found at paragraphs [0044] and [0003], respectively, of the specification.

In claim 13, the Examiner has objected to the phrase "as set out" in line 2 and the term "and" at the end of line 3. Applicants have amended claim 13 to delete the text in question.

The Examiner has objected to the phrases "an amino acid at position 21" and "an amino acid at position 28" in claims 14 and 15. Applicants have amended both claims to recite "the amino acid at . . ."

The Examiner has objected to the phrase "amino acid 50 to 56" in claim 16. Applicants have amended the claim to recite "amino acids 50 to 56."

The Examiner has objected to the phrase "amino acids substitutions" in claim 31. Applicants have amended the claim to recite "amino acid substitutions."

The Examiner has objected to the recitation of the term "from" in parts (a)-(f) of claim 35. Applicants have amended parts (a)-(f) to delete the term "from."

The Examiner has objected to claim 43 as duplicative of claim 42. Applicants have cancelled claim 43.

Indefiniteness

The Examiner has rejected claims 6-8 and 25-45 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter applicant regards as the invention.

Applicants respectfully traverse the Examiner's rejection of claims 6-8. The Examiner states that claims 6-8 are indefinite for reciting the "BAFF-R glycoprotein of claim 5, wherein the deletion . . ." The Examiner states claim 1 recites a "deletion," but claim 5 does not. Applicants note, however, that claim 5 depends from claim 1. "Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim." 37 C.F.R. § 1.75. Thus, claims 6-8, which depend from claim 5, properly refer to "the deletion" recited in claim 1 and incorporated by reference into dependent claim 5.

The Examiner states that claims 44 and 45 are indefinite because they recite the phrase "having an apparent affinity." The Examiner states that it is not clear if the glycoprotein has an affinity for BAFF or not. The Examiner suggests amending the claim to recite "having an affinity."

Applicants respectfully submit that claims 44 and 45 are clear. "Apparent affinity" is a widely-used term of art. As explained at paragraph [0060] of the instant specification, the term "apparent affinity" is used because the binding constant measured between BAFF-R and BAFF "includes an avidity component." Methods for measuring apparent affinity are described, e.g., in Example 3. One of skill in the art, reading the claim in view of the detailed disclosure, would have no trouble understanding the term or the metes and bounds of the claim.

The Examiner states that claims 25-45 are indefinite because it is not clear what amino acid sequence is encompassed by the phrase "comprising an amino acid sequence substantially as set out from amino acid 13 to amino acid 43" in claim 25. Applicants have amended claim 25 to a group of amino acid sequences similar to the group previously recited in claim 32, which is now cancelled.

The Examiner states that claims 12-18, 20, 22-24, 32, 35, and 37-38 are indefinite because the elements recited in claims 12, 20, 32, and 35 do not constitute proper Markush groups, citing M.P.E.P. § 2173.05(h). Applicants respectfully disagree, noting that the M.P.E.P. section cited by the Examiner explicitly acknowledges that elements of a Markush group "may be recited in the conventional manner, or alternatively. For example, if 'wherein R is a material selected from the group consisting of A, B, C and D' is a proper limitation, then 'wherein R is A, B, C or D' shall also be considered proper." Nonetheless, in the interest of advancing prosecution, Applicants have amended claims 12, 20, and 35 to recite the "conventional" Markush format (claim 32 is cancelled).

The Examiner states that claims 29-31 are indefinite because it is unclear which polypeptide of claim 25 they refer to. Claim 25 recites "a first polypeptide" and "a second polypeptide." Claims 29-31, which depend from claim 25, recite "an amino acid sequence substantially identical to SEQ ID NO:1," without indicating whether they refer to the first or second polypeptide of claim 25. As suggested by the Examiner, Applicants have amended claims 29 and 30 to recite "wherein the first polypeptide comprises . . ." Claim 31 is now independent.

In view of these amendments and remarks, Applicants submit that the claims are clear. Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection.

Enablement

The Examiner has rejected claims 23-32, 34, 37-38, 40-43, and 45 as allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. The Examiner states that the specification does not enable the skilled artisan to make and use the invention commensurate in scope with the claims.

Host cells

The Examiner acknowledges that the specification enables the skilled artisan to make and use the host cells recited in claims 23, 24, and 28 if they are isolated. Office Action of October 29, 2008, at 5. The Examiner has interpreted these claims, however, as "reading upon isolated host cells, as well as host cells in the context of host cells intended for gene therapy." The Examiner contends that the host cells in the latter "context" are not enabled.

Without acquiescing to the Examiner's rejection of the previously pending claims, Applicants submit that amended claims 23, 24, and 38 are enabled. As suggested by the Examiner, Applicants have these claims to recite "isolated host cells." Applicants note for the record that amended claims 23 and 38 are not limited by a particular use of the isolated host cells. Rather, these claims are intended to encompass any isolated host cell as recited in the claims, regardless of intended use. Thus, while Applicants maintain that the specification enables therapeutic uses of the claimed host cells, that is not required for claims 23 and 38 to be enabled. When the claim in questions is drawn to a composition, without limitation to any particular use, the first paragraph of 35 U.S.C. § 112 only requires the specification to enable a single use. See M.P.E.P. § 2164.01(c) ("if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention."). As the Examiner acknowledges, the specification enables at least the use of isolated host cells to produce BAFF-R glycoprotein, e.g., as described in claim 24. Thus, claims 23, 24, and 38 are enabled.

"Comprising an amino acid sequence . . ."

The Examiner acknowledges that the specification is "enabling for a BAFF-R fusion protein comprising a first polypeptide comprising the amino acid sequence from amino acid 13 (or 14) to amino acid 43 of SEQ ID NO:1." Office Action, at 5. But the Examiner has rejected claims 25-32, 34, 37, 38, 40, 42, 43, and 45 for reciting the phrase "an amino acid sequence." Because these claims recite the word "an," rather than the word "the," the Examiner concludes that they encompass "variants with any number of deletions, substitutions, or additions" and "fragments . . . including sequences

only 2 amino acids in length." The Examiner contends that such variants and fragments are not enabled.

Without acquiescing to the Examiner's rejection of the previously pending claims, Applicants submit that the amended claims are enabled. Applicants have amended claim 25 to recite a Markush group (in "conventional" format) consisting of the sequences previously recited in claim 32, which is now cancelled. This overcomes the Examiner's rejection of claim 25 and dependent claims 26, 27, 34, 37, 38, 40, 42, 43, and 45. Applicants have amended claims 28-30 to recite "wherein the first polypeptide comprises amino acids 8 to 49," "13 to 43," or "14 to 43" (respectively). Applicants have also rewritten claim 31 as an independent claim and cancelled claim 32. Applicants submit that these amendments overcome the Examiner's rejection of claims 25-32, 34, 37, 38, 40, 42, 43, and 45.

Pharmaceutical composition comprising a nucleic acid

The Examiner has rejected claim 41, stating that the specification does not enable the skilled artisan to make and use a pharmaceutical composition comprising a nucleic acid encoding a BAFF-R glycoprotein. Without acquiescing to the Examiner's rejection, Applicants have cancelled claim 41.

Methods for treating an immunological disorder

The Examiner has rejected claims 42 and 43 for reciting a "method for treating an immunological disorder." The Examiner states that the specification only enables treatment of "an autoimmune disorder characterized by an elevated BAFF level." Office Action, at 5.

Without acquiescing to the Examiner's rejection of claim 42 as previously pending, Applicants submit that amended claim 42 is enabled (as noted above, Applicants have cancelled claim 43). As amended, claim 42 recites a method for treating an autoimmune disease or a B cell cancer. The references cited by the Examiner explicitly recognize the rationale for using a BAFF antagonist to treat these indications. Schneider and Tschopp state that the "BAFF system is a promising target for the treatment of autoimmune diseases." Page 57, Abstract. Tangye et al. state that by targeting BAFF, "it should now be possible to improve treatment of antibody-mediated autoimmune diseases and B cell malignancies in a manner similar to the way anti-CD20 mAb (Rituximab) revolutionized therapy of RA and NHL." Page 313. Applicants have demonstrated that the disclosed BAFF-R glycoproteins bind to BAFF (see, e.g., Examples 3, 4, and 9) and inhibit BAFF from binding to B cells and delivering a pro-survival signal (see, e.g., Examples 5, 7, and 8). In light of (1) Applicants' data showing that the disclosed BAFF-R glycoproteins are BAFF antagonists and (2) the expectations in the art regarding the therapeutic applicability of BAFF antagonists as a class, the skilled artisan would expect that autoimmune diseases and B cell cancers could be treated by administering the disclosed BAFF-R glycoproteins. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 42 for lack of enablement.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and timely allowance of the claims.

Applicants invite the Examiner to call the undersigned Applicants' representative with any questions or comments.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 06-0916.

Respectfully submitted,

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Dated: January 9, 2009

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